rubella virus in serum. The identification aids in the diagnosis of rubella (German measles) or confirmation of a person's immune status from past infections or immunizations and provides epidemiological information on German measles. Newborns infected in the uterus with rubella virus may be born with multiple congenital defects (rubella syndrome).

(b) *Classification*. Class II. The special controls for this device are:

(1) National Committee for Clinical Laboratory Standards':

(i) 1/LA6 ''Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Speciment Handling, and Use of the Test Products in the Clinical Laboratory, October 1997,''

(ii) 1/LA18 ''Specifications for Immunological Testing for Infectious Diseases, December 1994,''

(iii) D13 ''Agglutination Characteristics, Methodology, Limitations, and Clinical Validation, October 1993,''

(iv) EP5 ''Evaluation of Precision Performance of Clinical Chemistry Devices, February 1999,'' and

(v) EP10 ''Preliminary Evaluation of the Linearity of Quantitive Clinical Laboratory Methods, May 1998,''

(2) Centers for Disease Control's:

(i) Low Titer Rubella Standard,

(ii) Reference Panel of Well Characterized Rubella Sera, and

(3) World Health Organization's International Rubella Standard.

[47 FR 50823, Nov. 9, 1982, as amended at 52 FR 17734, May 11, 1987; 65 FR 17144, Mar. 31, 2000]

§ 866.3520 Rubeola (measles) virus serological reagents.

(a) *Identification*. Rubeola (measles) virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rubeola virus in serum. The identification aids in the diagnosis of measles and provides epidemiological information on the disease. Measles is an acute, highly infectious disease of the respiratory and reticuloendothelial tissues, particularly in children, characterized by a confluent and blotchy rash.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 54 FR 25047, June 12, 1989; 66 FR 38792, July 25, 2001]

§ 866.3550 *Salmonella* spp. serological reagents.

(a) *Identification*. *Salmonella* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Salmonella* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Salmonella* spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of salmonellosis caused by bacteria belonging to the genus *Salmonella* and provides epidemiological information on this disease. Salmonellosis is characterized by high grade fever (''enteric fever''), severe diarrhea, and cramps.

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59227, Nov. 3, 1998]

§ 866.3600 *Schistosoma* spp. serological reagents.

(a) *Identification*. *Schistosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Schistosoma* spp. in serum. The identification aids in the diagnosis of schistosomiasis caused by parasitic flatworms of the genus *Schistosoma*. Schistosomiasis is characterized by a variety of acute and chronic infections. Acute infection is marked by fever, allergic symptoms, and diarrhea. Chronic effects are usually severe and are caused by fibrous degeneration of tissue around deposited eggs of the parasite in the liver, lungs, and central nervous system. Schistosomes can also cause schistosome dermatitis (e.g.,